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Docket No.: BSX 228
(10207709)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Peter J. SHANK et al.

Application No.: 10/720,176

Confirmation No.: 4334

Filed: November 23, 2003

Art Unit: 3738

For: COMPOSITE STENT WITH INNER AND
OUTER STENT ELEMENTS AND METHOD
OF USING THE SAME

Examiner: David A. Izquierdo

TRANSMITTAL LETTER

Customer Service Window
U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, Virginia 22314

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced
appealed patent application:

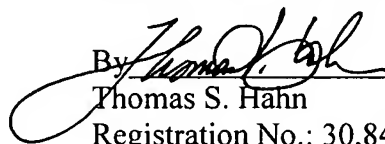
Reply Brief (37 CFR § 41.41), with Supplemental Claims Appendix.

No request for oral argument is being filed.

The Director is hereby authorized to charge any deficiency in fees that should be filed
with this submission to Deposit Account No. 06-2375, under Order No. BSX 228. A
duplicate copy of this paper is enclosed.

Dated: December 17, 2007

Respectfully submitted,

By 
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For: COMPOSITE STENT WITH INNER AND
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**REPLY BRIEF
(37 CFR § 41.41)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief, in accordance with 37 C.F.R. § 41.41, is filed in response to the Examiner's Answer mailed October 17, 2007 ("Answer").

I. APPEAL BRIEF ACKNOWLEDGED AS ADDRESSING REQUIRED MATTERS

The first seven sections of the Answer acknowledge that the Appeal Brief filed July 16, 2007 addresses those matters required by 37 CFR § 41.37(c)(1)(i)-(vi) & (viii). It further is acknowledged in the Answer that based on where the Examiner can confirm facts from the

prosecution history for this application the seven cited matters, except for the 37 CFR § 41.37(c) (1)(i)-(vi) & (vii) (Claims Appendix), are correctly addressed in the Appeal Brief. With respect to the Claims Appendix, included as pages 18-20 of the filed Appeal Brief, it correctly is pointed out in the Answer that dependent claim 22, which is involved in this Appeal, was omitted. In compliance with 37 CFR § 41.37(c)(1)(iii) the Appeal Brief lists the status of claims as including dependent claim 22 as a pending, rejected claim that is being appealed. The failure to list claim 22 in the filed Claims Appendix was inadvertent, and to correct this failure an Amended Claims Appendix Under 37 CFR § 41.37(c)(1)(viii) including claim 22 is filed herewith.

II. ASSERTED PRIOR ART AND PENDING CLAIM REJECTIONS

Sections 8 and 9 of the Answer respectively list the prior art patent of record that is asserted as evidence in support of outstanding claim rejections, and the grounds for rejection applied to the appealed claims. The patent of record listed in section 8 is: U.S. Patent 6,656,216 (“Hossainy *et al.*”) The grounds of rejection set out in section 9 of the Answer are a verbatim reproduction of the rejection reported in the final Office action mailed November 29, 2006. No new grounds are asserted in the Answer.

III. RESPONSE TO ARGUMENT

Hossainy *et al.* Fails To Anticipate Appealed Claims

In section 10 of the Answer the Examiner argues that the appealed claims are anticipated by Hossainy *et al.* because “there would be no reason why the band as described by Hossainy cannot be characterized as a stent” (Ans., p. 5). There are such reasons, and, therefore, the Examiner’s argument is flawed.

The band that is being referred to is the Hossainy *et al.* element number 209 structure (See, Ans., section 9, p.3). This argument that Hossainy *et al.* band 209 can “be characterized as a stent” is asserted to address the fact that appealed claimed subject matter covers a composite stent structure having: (i) a self-expanding metal stent within a bioabsorbable stent (e.g., independent claims 23 and 29); (ii) an inner stent engageable with an outer stent (e.g., independent claims 28 and 33); or (iii) a first stent engageable within a second stent (e.g., independent claim 30). All appealed independent claims cover a pair of stents forming a composite double stent structure.

It is not disputed that Hossainy *et al.* disclose a single stent structure (Appeal Brief, p. 12). Hossainy *et al.*, however, do not disclose or suggest any double stent structure. The Hossainy *et al.* band 209 is not disclosed as being a stent, nor do the Hossainy *et al.* disclosures suggest that band 209 is a stent. As such, Hossainy *et al.* do not disclose or suggest any composite stent structure, and, therefore, Hossainy *et al.* do not anticipate claimed subject matter.¹ In fact, Hossainy *et al.* explicitly teach away from band 209 being a stent structure.

The double stent structures covered by the appealed claims are disclosed in the filed specification as being “support structures for body orifices, cavities, etc.” (Appeal Brief, p. 10)² In contradistinction, Hossainy *et al.* disclose that their bands 209 are “viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time.” (Emphasis added, col. 3, lines 44-49) In context, the restoring forces

¹ “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 629, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

² Additionally, see Appeal Brief section VII (A) “Applicant’s Invention”, and filed specification paragraph 0021. 55147971.1

that bands 209 apply about the Hossainy *et al.* encircled stent are without exception inward directed forces that result in bands 209 being incapable of maintaining or contributing to maintaining an opening in a body cavity, i.e., providing support to a cavity. Hossainy *et al.* thereby teach away from bands 209 being stent structures. The Hossainy *et al.* disclosed devices exclusively are single stent structures.

Instead of addressing the Hossainy *et al.* teaching that bands 209 “typically exert a gradual and weak *restoring force*”, the Examiner in the Answer ignores this fact and argues that claim language nowhere mentions “the outer stent being capable of applying a radially outward force” (Ans., p.4). What the appealed claims cover are double stent structures, i.e., a bioabsorbable stent within a self-expanding metal stent, an outer stent within an inner stent, or a first stent within a second stent. No distinction is recited in the appealed claims between the paired stents being both stents. As such both provide support to maintain an opening as is disclosed in the specification.

With respect to filed specification disclosures, it is argued in the Answer that the “Applicant has described a replacement outer stent which is urged into position by an inner [self-expanding metal stent]” (Ans. p. 4). Specifically, specification paragraph 0016 is cited here in the Answer for disclosures concerning “the outer element [being], for example a bioabsorbable stent typically constructed of a relatively non-resilient material such that the outer bioabsorbable stent may not be self-expanding..., and ... a removable self-expanding metal stent (SEMS) [may be] used to urge and maintain the position of the outer element in the body lumen.” The claimed outer element indeed is described here in the specification as not necessarily being a self-expanding structure, but it also is described here as being typically made of a “non-resilient material.” In being described as being typically made of a non-resilient material this outer stent

is disclosed as being capable of providing support that results from being made of a material that when expanded would not exert forces to return the structure to its original contracted shape. This fact is further supported by disclosures in specification paragraph 0038, that also are cited in the Answer. Specifically, cited at page 4 of the Answer is disclosure from specification paragraph 0038 of “[a]nother advantage of the present invention is that the outer element is not required to support the lumen wall by itself.” The next sentence from the specification further clarifies this disclosure. The next sentence reads: “The inner element may assist the outer element in this respect.” In context, the stated “respect” is the inner element assisting the outer element in supporting the lumen wall. In contradiction to the Answer, the specification here, as elsewhere, discloses the outer element, or stent, as being a structure used to support a lumen wall and not as being a device that would exert a restoring or collapsing force on an encircled stent.

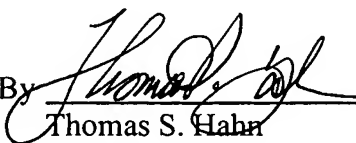
Hossainy *et al.* disclose, without exception, that their band 209 “typically exert[s] a gradual and weak restoring force,” which precludes their band 209 from being able to provide support for a lumen wall as do the double a stents as covered in all appealed claims. As such, Hossainy *et al.* without a disclosed or suggested double stent structure fails as an anticipation reference.

IV. CONCLUSION

Accordingly, for the reasons set out in the Appeal Brief and this Reply Brief, none of the appealed claims are anticipated by the asserted prior art. Therefore, the Examiner's rejections should be reversed.

Date: December 17, 2007

Respectfully submitted,

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V. SUPPLEMENTAL CLAIMS APPENDIX

A copy of claims involved in this Appeal for Application Serial No. 10/720,176 are listed below.

Claim 2 (Previously Presented): The composite stent of claim 28 wherein said outer stent and said inner stent are deployed separately and attached *in-vivo*.

Claim 3 (Previously Presented): The composite stent of claim 28 wherein said inner and said outer stents are inserted within the body lumen as a unit.

Claim 7 (Previously Presented): The composite stent according to claim 28 wherein said inner stent is configured to provide a radially outward bias so as to position said outer stent into engagement with the body lumen.

Claim 22 (Previously Presented): The composite stent of claim 28 further including a covering on one of said outer stent and said inner stent.

Claim 23 (Previously Presented): A composite stent comprising:

a bioabsorbable stent; and

a self-expanding metal stent releasably engageable within said bioabsorbable stent for insertion within a body lumen as a unit, said self-expanding metal stent biased to position said bioabsorbable stent into engagement with the body lumen.

Claim 24 (Previously Presented): The stent according to claim 23 wherein said bioabsorbable stent comprises a bioabsorbable ploymer.

Claim 28 (Previously Presented): A composite stent comprising:

an outer stent, said outer stent being a bioabsorbable stent, and said outer stent being open at opposite ends and having an outer surface engageable with an inner surface of a body lumen; and

an inner stent, said inner stent being a self-expanding metal stent, and said inner stent being open at opposite ends, said inner stent engageable with said outer stent to form a composite structure insertable within the body lumen, said inner stent configured to assist said outer stent in retaining a position of the outer stent within the body lumen.

Claim 29 (Previously Presented): A method of treatment comprising the steps of:

inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being made of a self-expanding metal, said inner stent being within an outer stent said outer stent being made of a bioabsorbable material;

expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen; and

allowing for normal functioning of the body lumen by transporting a bodily substance through said composite stent structure.

Claim 30 (Previously Presented): A composite stent comprising:

a first stent; and

a second stent engageable with said first stent to form a composite structure insertable within a body lumen, said second stent configured to assist said first stent in retaining a position of the first stent within the body lumen.

Claim 31 (Previously Presented): The composite stent of claim 30 wherein said first stent is a bioabsorbable stent.

Claim 32 (Previously Presented): The composite stent of claim 30 wherein said second stent is a self-expanding metal stent.

Claim 33 (Previously Presented): A method of treatment comprising the steps of:
inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being within an outer stent; and,

expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen.

Claim 34 (Previously Presented): The method of claim 33 wherein said inner stent is a self-expanding metal stent.

Claim 35 (Previously Presented): The method of claim 33 wherein said outer stent is a bioabsorbable stent.